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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,475	07/29/2003	Joseph D. Artiss	AJC 201.1 US/10304772	4686
7590	09/02/2004			
Mary Anne Schofield Fulbright & Jaworski L.L.P. 801 Pennsylvania Avenue, N.W. Washington, DC 20004			EXAMINER FUBARA, BLESSING M	
			ART UNIT 1615	PAPER NUMBER

DATE MAILED: 09/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/628,475	ARTISS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 13-116 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-116 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/22/03 &amp; 06/10/04</u>   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

Examiner acknowledges receipt of preliminary amendment and remarks filed 12/22/03 and 12/24/03; petition filed 12/24/03; IDS filed 12/22/03 and 06/10/04. The petition to make special was granted.

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claim 80 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing fat, does not reasonably provide enablement for preventing fat absorption. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. To “prevent” is to keep from happening.

For rejections under 35 U.S.C. 112, first paragraph, the following factors are considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988):

I) Nature of invention.

II) State of prior art.

III) Level of ordinary skill in the art.

IV) Level of predictability in the art.

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V) Amount of direction and guidance provided by the inventor.

VI) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

I. Nature of the invention:

The claims are drawn to method for reducing the bioavailability of fat in a fat containing food product by complexing the amount of fat in the food product with  $\alpha$ -cyclodextrin.

Applicants' specification does not discuss or show with data how the recurrence of migraine has been kept from happening.

II. State of the prior art:

The prior art does not disclose case supported by data showing that absorption of fat in or by a subject has been kept from happening and how long the fat has been kept from being absorbed by a subject in how many subjects has the absorption of fat been stopped or kept from happening.

III. Level of Ordinary Skill in the art:

The level of ordinary skill in the art is high. Applicants' specification does not enable the public to practice the art of keeping fat from being absorbed.

IV. Level of predictability:

Since applicants' specification does not show the stoppage or exclusion or keeping fat-absorption from taking place and for how long a subject is kept from absorbing fat, the ability of the person of skill in the art is challenged to extrapolate the disclosed or known results to the claimed invention with little or no predictability. The lower the predictability, the higher the direction and guidance that must be provided by the applicants. In the instant invention the

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predictability is very low and consequently, the need for the higher levels of direction and guidance by the applicants.

V. Amount of direction and guidance provided by the inventors:

The amount of direction and guidance provided by the applicants is limited to complexing  $\alpha$ -cyclodextrin with fat. There is no evidence in the specification that established correlation between administration of fat  $\alpha$ -cyclodextrin complexed food product and keeping fat from being absorbed. See Ex parte Mass, 9 USPQ2d 1746, 1987.

VI. Quantity of experimentation needed to make or use the invention based on the content of the disclosure:

The quantity of experimentation required to use the invention as claimed, based on applicants' disclosure would be undue burden because, one of ordinary skill in the art would have to perform significant amount of experimentation with a large number of subjects and for reliable duration of time during which fat is stopped or kept from being absorbed by a subject.

4. Claims 13-17, 62-76, 80 and 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is not clear. It appears that  $\alpha$ -cyclodextrin should be  $\alpha$ -cyclodextrin-fat-complex since the  $\alpha$ -cyclodextrin forms a complex with the fat. The fat is in excess and there will not be any cyclodextrin left for removal.

Claim 17 is directed to combining  $\alpha$ -cyclodextrin and fat and the cyclodextrin is in the form of a pill, tablet, powder, capsule, liquid, cracker, wafer or confection. It is not clear how the pill, tablet or capsule is mixed or combined with the food.

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Claim 80 is confusing because the claim is not clear as to what the claim is directed to.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 13-116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (JP 6094912, provided by applicants on PTO Form 1449).

Suzuki discloses compositions that are administered to subjects to reduce fat and the composition comprises  $\alpha$ -cyclodextrin present in amounts of 10-40%. Suzuki does not determine the amount of fat contained in the food before administering the  $\alpha$ -cyclodextrin. Regarding the forming of cyclodextrin-fat complex, it is inherent that a complex would form when  $\alpha$ -cyclodextrin come in contact with a fat. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the composition of Suzuki to reduce fat. One having ordinary skill in the would have been motivated to administer  $\alpha$ -cyclodextrin to a subject in need thereof with the expectation of reducing fat.

***Drawings***

7. The drawings are objected to as failing to comply with 37 CFR 1.84; copy of Patent Drawing Review.

Other Matters:

Seafood and fish sticks are generally not considered as a meat product. It is not clear what makes up the deli slices. French fries and nut butters are listed as vegetables and generally

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these food items are not listed as vegetables. Claims 91-94 recite "before or during consumption of a meal." It appears that the  $\alpha$ -cyclodextrin is consumed before a meal or is taken with the meal. The claims may be amended to recite ---consumed before a meal or with the meal---.

8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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